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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,229	03/18/2005	Daisuke Itoh	2005_0470A	6230

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EXAMINER
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WOOD, ELLEN S

ART UNIT	PAPER NUMBER
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1782

NOTIFICATION DATE	DELIVERY MODE
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05/17/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/528,229	<b>Applicant(s)</b> ITO ET AL.	
	<b>Examiner</b> ELLEN S. WOOD	<b>Art Unit</b> 1782	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/10/2010; 11/09/2009</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's arguments, filed 02/12/2010, with respect to claims 1-7 and 9-12 have been fully considered and are persuasive. The rejection of claims 1-7 and 9-12 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shiiki et al. (EP0925915, hereinafter "Shiiki").has been withdrawn.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1 recites the limitation "by stretching the glycolic acid homopolymer" in line

4. The claim discloses that the crystalline aliphatic polyester comprises glycolic acid homopolymer. The claim does not limit the crystalline aliphatic polyester to a glycolic acid homopolymer until claim 9. Thus, there is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiiki et al. (EP0925915, hereinafter "Shiiki") in view of Kawakami et al. (US 6,159,416, hereinafter "Kawakami").

In regards to claims 1-7, Shiiki discloses a gas barrier multi-layer hollow container with a polyglycolic acid layer [0028]. The polyglycolic acid useful is a polymer containing a repeating unit represented by the following formula (1):



This is the formula of the instant applicant's recurring unit of the glycolic acid polymer (pg. 7 lines 19-23). Shiiki discloses that the crystalline aliphatic polyester is glycolic acid homopolymer [0031]. The blow molding process to make the hollow container includes a stretch blow molding process [0052]. Thus, the container has a layer that is a stretched product of crystalline aliphatic polyester.

In regards to claims 9, Shiiki discloses that the aliphatic polyester layer is comprised of a glycolic acid homopolymer [0065 and table 1].

In regards to claim 10, Shiiki discloses that the multi-layer hollow container has a layer of polyglycolic acid [0013], thus the polyglycolic acid is in the form of a film.

In regards to claim 11, Shiiki discloses that the polyglycolic acid is a layer of a hollow container [0013], thus in the form a bottle.

In regards to claim 12, Shiiki discloses that various thermoplastic resin layers (polymer layer) may be laminated to the polyglycolic acid layer [0019-0020].

Shiiki does not disclose that the aliphatic polyester has a crystal melting point higher by at least 3<sup>0</sup>C and 5<sup>0</sup>C than that of an un-stretched product, the sub-dispersion peak temperature, the main dispersion peak temperature and the orientation degree measured by wide-angle X-ray diffractometry.

Shiiki discloses that when the T<sub>m</sub> of the polyglycolic acid is lowered, the processing temperature of the polymer can be lowered, therefore thermal decomposition upon melt processing can be reduced [0031]. The crystallization rate of the polyglycolic acid can also be controlled by copolymerization to improve its extrudability and stretchability [0031]. Shiiki discloses that the "stretch blow molding process" is a process in which stretching is conducted upon blow molding, thereby orienting the molecular chain of a polymer to enhance the physical properties of the polymer such as transparency, strength, elastic modulus and gas barrier properties [0052]. In order to enhance such physical properties, it is essential to keep a parison at a temperature not higher than its melting point, but not lower than its glass transition point upon stretch blow molding [0052].

Shiiki is silent with regards to the stretched product being obtained by stretching the glycolic acid homopolymer at 45-60<sup>0</sup>C at a stretching ratio exceeding 3x3 times.

Kawakami discloses a polyglycolic acid film formed from a thermoplastic resin material which comprises polyglycolic acid having a repeating unit represented by the following formula (1):



(abstract).

The polyglycolic acid film can be formed into a stretch blow molded container (col. 12 lines 29-33). The temperature conditions for the stretch blow molding are  $T_g$  70°C or lower (col. 12 lines 64-65). The resin temperature upon stretch blow molding is controlled to 30-100°C (col. 13 lines 26-28). The preform is stretched at a draw ratio higher than one time but not higher than 10 times in a machine direction (col. 13 lines 29-30). The blow up ratio is generally 1.5-10 (col. 13 lines 37-38).

It would be obvious to one of ordinary skill at the time of the invention to substitute the stretch blow molding conditions of Kawakami for the stretch blow molding conditions of Shiiki, because the films of Shiiki and Kawakami contain a substantially similar polyglycolic acid film. Also, the stretching conditions of Kawakami provide the correct orientation of the molecular chain, therefore providing a container that exhibits sufficient tensile strength, and also has sufficient barrier properties, heat resistance and transparency (col. 13 lines 39-45).

It should be noted that the crystal melting point, sub-dispersion peak temperature, main dispersion peak temperature, and the orientation degree are result effective variables. As orientation of the molecular chain increases, the degree of crystallinity of the polymer becomes sufficient to prevent the formation of harmful coarse spherulites that may result in insufficient properties of the polymer film. It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a container with optimal values for the crystal melting point, sub-dispersion peak temperature, main dispersion peak temperature, and the orientation degree since

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it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 1-7 and 9-12 have been considered but are moot in view of the new ground(s) of rejection.

7. The applicant argues that Shiiki does not disclose the stretching ratio exceeding 3x3 at a stretching temperature at 45-60<sup>0</sup>C.

In response, the secondary reference, Kawakami, discloses a process for stretch blow molding polyglycolic acid polymer films. The stretch blow molding of the films is at a temperature that is controlled to 30-100<sup>0</sup>C (col. 13 lines 26-28). The preform is stretched at a draw ratio higher than one time but not higher than 10 times in a machine direction (col. 13 lines 29-30). The blow up ratio is generally 1.5-10 (col. 13 lines 37-38). Kawakami discloses that it is necessary to blow the films in this temperature range and with a high stretch ratio, because if not, then the orientation of the molecular chain becomes insufficient, so that there is a possibility that the degree of crystallinity of the polymer may be insufficient, and the formation of harmful coarse spherulites may hence be brought, resulting in a stretch blow molded container which cannot exhibit sufficient tensile strength, and also has insufficient barrier properties, heat resistance and transparency (col. 13 lines 39-45). Thus, the secondary reference, Kawakami, provides the motivation to use a stretching ratio exceeding 3x3 at a stretching temperature at 45-

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60°C when using polyglycolic acid polymer films, in order to provide a container with excellent mechanical and barrier characteristics.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLEN S. WOOD whose telephone number is (571)270-3450. The examiner can normally be reached on M-F 730-5 with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571)272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ELLEN S WOOD/  
Examiner, Art Unit 1782

/Rena L. Dye/  
Supervisory Patent Examiner, Art Unit 1782